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B. FIELDS SEARCHED

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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

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BIOSIS, EPO-Internal, MEDLINE, EMBASE, WPI Data, PAJ

Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
US 6 024 938 A (BORNSTEIN MICHAEL ET AL) 15 February 2000 (2000-02-15)	1,3-5, 13-15, 17-19
abstract column 9, line 4-29 column 11, last paragraph	1-21
EP 1 174 148 A (YAMANOUCHI PHARMA CO LTD) 23 January 2002 (2002-01-23) paragraph '0028! paragraph '0031! claims 1,5,6,8-10	1,3-5, 13,14 1-23
-/	
	US 6 024 938 A (BORNSTEIN MICHAEL ET AL) 15 February 2000 (2000-02-15) abstract column 9, line 4-29 column 11, last paragraph EP 1 174 148 A (YAMANOUCHI PHARMA CO LTD) 23 January 2002 (2002-01-23) paragraph '0028! paragraph '0031! claims 1,5,6,8-10

Further documents are listed in the continuation of box C.	Patent family members are listed in annex.
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Date of the actual completion of the International search 4 May 2004	Date of mailing of the international search report 26/05/2004
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European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31–70) 340–2040, Tx. 31 651 epo nl, Fax: (+31–70) 340–3016	Lechner, O



C/Continuation), DOCUMENTS CONSIDERED TO BE RELEVANT								
Category • Citation of document, with indication, where appropriate, of the relevant passages Relevant to claim No.								
Category Citation of document, with indication, where appropriate, of the relevant passages								
US 6 171 586 B1 (ONGPIPATTANAKUL BOONSRI ET AL) 9 January 2001 (2001-01-09) column 22, line 18-61 table 1 column 26, line 59-63 table 11 claims 1-21	1,3-5,13							
WO 01/47554 A (HAYASAKA AKIRA ;KOGA AKIKO (JP); YAMAZAKI TADAO (JP); CHUGAI PHARM)	1,3-5,13							
& EP 1 254 666 A 6 November 2002 (2002-11-06) abstract paragraphs '0078!,'0089!,'0090!,'0108!,'0115!	1-23							
WO 98/56418 A (GENENTECH INC)	1,3-5,13							
claim 23 claim 12 page 39, last paragraph	1-23							
WO 97/04801 A (GENENTECH INC) 13 February 1997 (1997-02-13) page 19-21 page 28, last paragraph -page 29, paragraph 2	1,3-5,13							
US 5 945 098 A (SARNO MARIA ERLINDA C ET AL) 31 August 1999 (1999-08-31) claims 1-15	1,3-5							
WO 02/12502 A (CENTOCOR INC) 14 February 2002 (2002-02-14) page 38, paragraphs 1,3,4 page 39, paragraph 2 page 40, paragraphs 5,6	1-23							
US 6 090 382 A (HOOGENBOOM HENDRICUS R J M ET AL) 18 July 2000 (2000-07-18) cited in the application column 21, line 1-6,23,49 column 23, line 62-67 claims 1-10	1-23							
	US 6 171 586 B1 (ONGPIPATTANAKUL BOONSRI ET AL) 9 January 2001 (2001-01-09) column 22, line 18-61 table 1 column 26, line 59-63 table 11 claims 1-21 WO 01/47554 A (HAYASAKA AKIRA ;KOGA AKIKO (JP); YAMAZAKI TADAO (JP); CHUGAI PHARM) 5 July 2001 (2001-07-05) & EP 1 254 666 A 6 November 2002 (2002-11-06) abstract paragraphs '0078!, '0089!, '0090!, '0108!, '0115! WO 98/56418 A (GENENTECH INC) 17 December 1998 (1998-12-17) claim 23 claim 12 page 39, last paragraph WO 97/04801 A (GENENTECH INC) 13 February 1997 (1997-02-13) page 19-21 page 28, last paragraph -page 29, paragraph 2 US 5 945 098 A (SARNO MARIA ERLINDA C ET AL) 31 August 1999 (1999-08-31) claims 1-15 WO 02/12502 A (CENTOCOR INC) 14 February 2002 (2002-02-14) page 38, paragraphs 1,3,4 page 39, paragraph 5,6 US 6 090 382 A (HOOGENBOOM HENDRICUS R J M ET AL) 18 July 2000 (2000-07-18) cited in the application column 21, line 1-6,23,49 column 23, line 62-67 claims 1-10							



PCT/IB 03/04502

		PCT/IB 03/04502
C.(Continue	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	
Category °	Citation of document, with Indication, where appropriate, of the relevant passages	Relevant to claim No.
A	CLELAND JEFFREY L ET AL: "A specific molar ratio of stabilizer to protein is required for storage stability of a lyophilized monoclonal antibody" JOURNAL OF PHARMACEUTICAL SCIENCES, vol. 90, no. 3, March 2001 (2001-03), pages 310-321, XP002278944 ISSN: 0022-3549 abstract	1-23
Α	HILLGREN ANNA ET AL: "Protection mechanism of Tween 80 during freeze-thawing of a model protein, LDH." INTERNATIONAL JOURNAL OF PHARMACEUTICS. NETHERLANDS 26 APR 2002, vol. 237, no. 1-2, 26 April 2002 (2002-04-26), pages 57-69, XP002278945 ISSN: 0378-5173 the whole document	1-23
	·	
300	A:	

INTERNATION SEARCH REPORT

nal Application No
PCT/IB 03/04502

				FCI/IB	03/04302
Patent document cited in search report		Publication date		Patent family member(s)	Publication date
US 6024938	Α	15-02-2000	ZA	9505642 A	06-05-1997
EP 1174148	Α	23-01-2002	AU CA EP WO	4314900 A 2371427 A1 1174148 A1 0066160 A1	17-11-2000 09-11-2000 23-01-2002 09-11-2000
US 6171586	B1	09-01-2001	NONE		
WO 0147554	A	05-07-2001	AU EP WO US	2228901 A 1254666 A1 0147554 A1 2003124119 A1	09-07-2001 06-11-2002 05-07-2001 03-07-2003
WO 9856418	A	17-12-1998	AT AU CA DE DE DK EP ES JP WO	230277 T 740284 B2 8255998 A 2292730 A1 69810481 D1 69810481 T2 999853 T3 0999853 A1 2190087 T3 2002504907 T 9856418 A1	15-01-2003 01-11-2001 30-12-1998 17-12-1998 06-02-2003 25-09-2003 22-04-2003 17-05-2000 16-07-2003 12-02-2002 17-12-1998
WO 9704801	A	13-02-1997	UST AUU UR AA AU BEA CODE EN SILLPPONZZTO WOSAAS	6267958 B1 225185 T 716785 B2 6599296 A 715338 B2 6638196 A 9609743 A 2226575 A1 2226624 A1 1191490 A 69624116 D1 69624116 T2 841946 T3 0845997 A1 0841946 A1 2186796 T3 122733 A 122910 A 11510170 T 11510172 T 980335 A 313503 A 500539 A 841946 T 9704807 A1 2001014326 A1 9606075 A 9606240 A	31-07-2001 15-10-2002 09-03-2000 26-02-1997 20-01-2000 26-02-1997 02-03-1999 13-02-1997 13-02-1997 26-08-1998 07-11-2002 18-06-2003 10-02-2003 10-06-1998 20-05-1998 20-05-1998 16-05-2003 13-09-2001 23-05-2002 07-09-1999 07-09-1999 26-03-1998 28-01-2000 30-11-2001 28-02-2003 13-02-1997 16-08-2001 19-01-1998 23-01-1998
			US	2003202972 A1	30-10-2003

	Patent document cited in search report		Publication date		Patent family member(s)	Publication date
	WO 0212502	Α	14-02-2002	US	2003049725 A1	13-03-2003
1				AU	7922701 A	18-02-2002
1				BR	0113110 A	16-09-2003
				CA	2419205 A1	14-02-2002
				CN	1468308 T	14-01-2004
				EP	1309691 A2	14-05-2003
1				HU	0302376 A2	28-10-2003
				NO	20030620 A	31-03-2003
				. WO	0212502 A2	14-02-2002
	US 6090382	Α	18-07-2000	AT	239041 T	15-05-2003
ĺ				AU	722077 B2	20-07-2000
				AU	2122997 A	28-08-1997
1				BG	102755 A	31-05-1999
				BG	107537 A	30-09-2003
1				BR	9707379 A	13-04-1999
				CA	2243459 A1	14-08-1997
1				CA	2389943 A1	14-08-1997
				CN	1215407 A	28-04-1999
1				CZ	9802476 A3	11-11-1998
1				DE	69721548 D1	05-06-2003
1				DE	69721548 T2	01-04-2004 25-08-2003
				DK Ep	929578 T3 1285930 A2	26-02-2003
1					0929578 A1	21-07-1999
Ì				EP Es	2198552 T3	01-02-2004
				HU	9901874 A2	28-09-1999
	•			JP	2000507810 T	27-06-2000
1				JP	2000307810 T 2003177130 A	27-06-2003
1				NO	983627 A	07-10-1998
				NO	20026202 A	07-10-1998
				NZ	331579 A	29-06-2001
				PL	328411 A1	18-01-1999
				PT	929578 T	30-09-2003
				SĪ	9720020 A ,B	31-10-1999
				SK	106298 A3	10-03-1999
				TR	9801532 T2	23-11-1998
1				WO	9729131 A1	14-08-1997
				ÜS	6258562 B1	10-07-2001
1				ÜS	2003219438 A1	27-11-2003
				ÜS	6509015 B1	21-01-2003